

rejection is not well taken. In Claim 1, Applicant claimed an active agent wherein "said active agent is *Hypericum perforatum*, a *Hypericum* extract, an extract of a species of the *Hypericum* genus other than *Hypericum perforatum*, a *Hypericum* constituent, a hypericin derivative or a hypericin analog." Claims 2-7 follow a similar manner of claiming in their use of the conjunction "or". The First Office Action objected to the use of "or" in the claims and stated that the proper method of claiming the active agents involved using the conjunction "and" (see First Office Action, pages 4-5).

Applicant respectfully submits that Section 2173.05(h), section II ("Or" Terminology) of the MPEP states that "[a]lternative expressions using 'or' are acceptable, such as 'wherein R is A, B, C, or D.'" Accordingly, Applicant respectfully submits that this basis of rejection be withdrawn because the present application follows this permitted mode of claiming.

The First Office Action also contained a rejection directed towards the language used in Claim 3 of the present application. In response to the rejection based upon the misspelled terms, Applicant has amended Claim 3. Applicant would further note that the replacement of these terms does not narrow the claim limitations as one with skill in the art would have known that "ischemic" and "diabetes" were the intended terms.

In response to the request to clarify the term "brain aging", Applicant submits that this term means the aging of the brain as a health disorder. Applicant respectfully submits that one skilled in the art would recognize this term for what it means and requests that this basis of rejection be withdrawn.

Regarding the clarification requested for the inclusion in Claim 3 of migraine headaches and depression, Applicant respectfully notes that these have been removed from the amended Claim 3 and requests that this rejection be withdrawn as well.

Claims 1-17 and 22 have also been rejected under 35 U.S.C. 102(b) as anticipated by DE 1692045, BE 654914, or EP 0847756. The First Office Action states that these references each teach an extract from *Hypericum perforatum* that is used to treat health disorders such as angina pectoris and hepatitis. The First Office Action also states that the use of the extract to treat hepatitis is considered to also treat health disorders such as angina pectoris since it is inherent that angina pectoris will also be treated. It is also stated that the method of using the extract is the same.

Regarding the DE 1692045 reference, Applicant respectfully submits that this ground of rejection has been obviated by the amendments made to Claim 1. Amended Claim 1 has been narrowed from an extract of *Hypericum perforatum* to "a methanol or ethanol extract of *Hypericum perforatum*" based upon the disclosure in the instant specification (see page 11, lines 20-22). Accordingly, Applicant respectfully requests that this ground of rejection be withdrawn.

103  
obvious  
- use EP  
1756  
for  
motivation

Regarding the BE 654914 reference, this reference discloses the use of a composition containing extracts from *Hypericum perforatum* and *Filipendula ulmaria*. Applicant respectfully notes that the present application does not claim a mixture of these two extracts and solely claims an extract from *Hypericum perforatum*.

clms.  
not  
limited

Furthermore, the present application deals specifically with a mechanism of action, T-type calcium channel blocking, whereas the BE 654914 reference makes no mention of

a mechanism of action at all. Therefore, Applicant respectfully requests that this ground of rejection be withdrawn. *inherent*

Regarding the EP 0847756 reference, this reference discloses the use of extracts of *Hypericum perforatum* for the treatment, prevention, or control of hepatitis C, chronic hepatitis, and infections of related viruses (See Col. 1, lines 5-9). This reference fails to anticipate the present application because infections of hepatitis viruses are not health disorders treatable with T-type calcium channel blockers. *inherent*

Accordingly, Applicant respectfully requests that this ground of rejection be withdrawn as well.

Finally, the First Office Action rejected Claims 1-17 and 22 under 102(e) as anticipated by Lavie et al (hereinafter "Lavie"). The First Office Action states that Lavie teaches an extract from *Hypericum perforatum* may be used to treat hepatitis. The Office Action further states that using the extract to treat health disorders like angina pectoris is also considered from its use to treat hepatitis as it is inherent that the angina pectoris will also be treated. Lastly, it noted that the method of using the extract was the same.

Again, Applicant respectfully submits that Lavie is not relevant to the present application. The claims of the present application are not directed towards the treatment of viruses. As stated previously, viruses are not treatable with T-type calcium channel blocking. Accordingly, Applicant respectfully requests that this rejection be withdrawn as well.

Additionally, regarding the EP 0847756 reference and the Lavie reference, Applicant notes that the Office Action appears to contain an inherency rejection. In

particular, the rejection states that the treatment of angina pectoris is inherent in the treatment of hepatitis with extract from *Hypericum perforatum*. Assuming that T-type calcium channel blockers could be used to treat hepatitis (which Applicant reiterates is not possible because T-type calcium channel blockers cannot be used to treat viruses), Applicant respectfully submits that the burden of proof required for a rejection by inherency has not been met.

Section 2112 of the MPEP reads that "[t]he fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic." The section continues by stating that "[t]o establish inherency, the extrinsic evidence must make clear that the missing descriptive matter is necessarily present in the thing described by the reference, and that it would be so recognized by persons of ordinary skill." The section concludes by noting that "[i]nherency, however, may not be established by probability or possibilities" and that the "mere fact that a certain thing may result from a given set of circumstances is not sufficient."

cite  
ex Parte  
Novitsky

The MPEP also states on this subject that "[i]n relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art."

Applicant respectfully submits that this burden of proof has not been met. The present application does not deal with the treatment of viruses, including hepatitis. Furthermore, viruses are not treatable with T-type calcium channel blockers. Applicant is unable to locate any basis provided by the Examiner that it is inherent that angina


pectoris would be treated through the administration of T-type calcium blockers to a hepatitis patient. Further, Applicant was not supplied with any information that such is supported by a basis in fact and/or technical reasoning. Additionally, no evidence was presented that one of skill in the art would recognize that an extract used to treat viruses such as hepatitis could be used as T-type calcium channel blockers. Accordingly, Applicant respectfully requests that this ground of rejection be withdrawn as well.

As Applicant believes that the present application is now in a condition for allowance, Applicant respectfully requests that all grounds of rejection be withdrawn in this case.

In the event this paper is not timely filed, Applicant hereby petition for an appropriate extension of time. The fee for this extension may be charged to our Deposit Account No. 01-2300.

Please charge any fee deficiency or credit any overpayment to Deposit Account No. 01-2300.

Respectfully submitted,

  
D. Daniel Dzara, Jr.  
Registration No. 47,543

ARENT FOX KINTNER PLOTKIN & KAHN, PLLC  
1050 Connecticut Avenue, N.W.,  
Suite 600  
Washington, D.C. 20036-5339  
Tel: (202) 857-6000  
Fax: (202) 638-4810

## **MARKED UP COPY OF CLAIMS**

### **Claim 1**

(once amended) 1. A method of treating a health disorder treatable with a T-type calcium channel blocker in an animal in need of such treatment, comprising administering an effective amount of an active agent to said animal, wherein said active agent is *Hypericum perforatum*, a methanol or ethanol extract of *Hypericum* [extract], an extract of a species of the *Hypericum* genus other than *Hypericum perforatum*, a *Hypericum* constituent, a hypericin derivative or a hypericin analog, with the proviso that when the active agent is *Hypericum perforatum* or a methanol or ethanol extract of *Hypericum* [extract], said health disorder is not depression or migraine headache.

### **Claim 3**

(once amended) 3. The method of Claim 1, wherein the health disorder treatable with T-type calcium channel blockers is [depression,] chronic heart failure, congestive heart failure, ischemic [ischaemic] condition, arrhythmia, angina pectoris, hypertension, hypoinsulinemia, hyperinsulinemia, diabetes [diabete] mellitus, hyperaldosteronemia, epilepsy, [migraine headache,] brain aging, a neurodegenerative disease or preterm labor.